IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA ex rel. ROBERT WILLSON, RICHARD EHLERS, and CRAIG WATKINS Plaintiffs, v. PFIZER, INC., PHARMACIA CORPORATION; and G.D. SEARLE & CO., Defendants.	)	Case No. Complaint Filed Under Seal Pursuant to 31 U.S.C. § 3730

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COMPLAINT

Plaintiffs Robert Willson, Richard Ehlers, and Craig Watkins, for their Complaint, state and allege as follows:

Parties

1. Robert Willson, Richard Ehlers, and Craig Watkins (collectively, the "Relators") are residents of Johnson County, Kansas and Jackson County, Missouri, and are former employees of Pharmacia Corporation and G.D. Searle & Co. Relators have prepared and will serve with this Complaint a disclosure pursuant to 31 U.S.C. § 3730(2) of information in their possession and of which they are the original source.

2. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business in New York, New York. At all times relevant hereto, defendant Pfizer was in the business of manufacturing, marketing, selling and distributing the pharmaceutical products Celebrex® and Bextra® to physicians and the public, including business conducted in the District of Massachusetts.

3. From 2003 through early 2003, defendant Pharmacia Corporation ("Pharmacia") was a Delaware corporation with its principal place of business in Chicago, Illinois. Pharmacia was created in April 2000 as the result of a merger between Pharmacia & Upjohn and Monsanto Company. In April 2003, a merger was consummated between Pharmacia and Pfizer, with Pfizer being the surviving entity. At all times relevant hereto, defendant Pharmacia was in the business of manufacturing, marketing, selling and distributing the pharmaceutical products Celebrex® and Bextra® to physicians and the public, including business conducted in the District of Massachusetts. According to its internet website, Pfizer has a research and development facility located in Cambridge, Middlesex County, Massachusetts.

4. Defendant G.D. Searle & Co. ("Searle") is a Delaware corporation, with its principal place of business in Skokie, Illinois. At all times relevant hereto, defendant Searle was in the business of manufacturing, marketing, selling and distributing the pharmaceutical products Celebrex® and Bextra® to physicians and the public, including business conducted in the District of Massachusetts. In 1985, Searle was acquired by Monsanto Company, and became Monsanto Company's pharmaceutical business unit. In April 2000, Monsanto Company merged with Pharmacia & Upjohn, resulting in the creation of defendant Pharmacia.. In April 2003, a merger was consummated between defendants Pharmacia and Pfizer, with Pfizer being the surviving entity.

5. Defendants co-promoted the pharmaceutical products Celebrex® and Bextra® at all times relevant hereto.

Jurisdiction and Venue

6. Jurisdiction is proper in this Court pursuant to 31 U.S.C. § 3730.

7. Venue is proper in this Court pursuant to 31 U.S.C. §§ 3732.

Facts Common to All Counts

8. Celebrex® was approved by the FDA for marketing in 1998. Celebrex® received initial FDA marketing approval for treatment of pain associated with osteoarthritis and rheumatoid arthritis. In October 2001, Celebrex® received FDA marketing approval for treatment of acute pain.

9. Bextra® was approved by the FDA for marketing in 2001. Bextra® received FDA marketing approval for treatment of pain associated with osteoarthritis, rheumatoid arthritis and dysmennorrhea (menstrual pain). Bextra® never received FDA marketing approval for acute pain.

10. Celebrex® and Bextra® were not FDA approved for pre-surgical and post-surgical pain, heel pain, dental pain, chronic lower back pain, or general pain.

11. Relators were sales representatives who marketed Celebrex® and Bextra® to the medical community in the Western District of Missouri. They have first hand knowledge of defendants' marketing and sales tactics for Celebrex® and Bextra® nationwide.

12. Under federal law, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes other than those approved by the FDA. Such promotion is "off-label" and illegal.

13. Defendants formed a scheme to increase the sales of Celebrex® and Bextra® while avoiding the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses of these drugs. The scheme consisted of off-label promotion of Celebrex® and Bextra® in direct contravention of FDA rules and regulations.

14. The off-label marketing scheme included, among other things:

(a) training the Celebrex® and Bextra® sales force to promote the drugs off-label by having them participate in "grinders" where they were trained to promote the drugs for any and all kinds of pain through slogans such as "pain is pain";

(b) promotion of Celebrex® and Bextra® to doctors through the sales force for any and all kinds of pain through the "core message" with the slogan "pain is pain";

(c) promotion of Celebrex® and Bextra® to doctors who did not treat arthritic patients, such as emergency room doctors, podiatrists, oncologists, and even psychiatrists for any and all kinds pain;

(d) promotion of Celebrex® and Bextra® to doctors through the sales force for any and all kinds of pain by giving doctors "pain packs" that consisted of fourteen sample pills of Celebrex® and Bextra® to be prescribed to patients for any type of pain;

(e) providing illegal kickbacks to prescribing physicians who prescribed Celebrex® and Bextra® "off-label" to patients including direct payments and gifts to doctors and their families; all-expense paid trips for doctors; and speaking fees to doctors;

(f) paid incentives to sales representatives who successfully marketed Celebrex® and Bextra® to prescribers for off-label use;

(g) promotion of Bextra® to doctors for pain management even though the drug was never approved for pain management;

(h) promotion of Celebrex® and Bextra® as being safer than over-the-counter traditional NSAID's with regard to gastrointestinal side-effects when in fact such drugs are no safer than traditional NSAIDs; and

(i) promotion of Celebrex® and Bextra® for formulary acceptance at government-run medical facilities (such as Kirkland Air Force Base) for off-label use for pre-operative and post-operative pain.

15. On information and belief, (i) Celebrex® and Bextra® are no more safe or efficacious for pain than traditional over-the-counter NSAIDs, (ii) Celebrex® and Bextra® are far more costly to purchasers than traditional over-the-counter NSAIDs and (iii) over 50% of prescriptions for Celebrex® and Bextra® during the period relevant to this Complaint were off-

label. A substantial portion of these off-label prescriptions were paid by the United States in the form of reimbursements made under the Medicaid program, 42 U.S.C. § 1396, *et seq.*, and through direct purchases by the United States Armed Services and Veterans Administration.

16. The statute applicable to the coverage of prescription drugs under the Medicaid program provides the States with the discretion to refuse to cover prescription drugs for off-label purposes. *See* 42 U.S.C. § 1396r-8(d)(1)(B). On information and belief, a significant number of states refuse to cover prescription drugs for off-label purposes under the Medicaid program.

Count I
False Claims in Relation to the Medicaid program

17. The allegations set forth in paragraphs 1-16 above are hereby incorporated by reference as though fully set forth herein.

18. As part of the illegal off-label promotion of Celebrex® and Bextra®, defendants instructed and caused their sales personnel to falsely represent to physicians that Celebrex® and Bextra® were safer than over-the-counter traditional NSAID's with regard to gastrointestinal side-effects.

19. As part of the illegal off-label promotion of Celebrex® and Bextra®, defendants instructed their respective sales forces to promote the drugs for any type of pain, not just the types of pain for which the drugs had been approved by the FDA.

20. As part of the illegal off-label promotion of Celebrex® and Bextra®, during the period of time when (a) Celebrex® was approved only for the treatment of pain associated with osteoarthritis and rheumatoid arthritis and (b) Bextra® was approved only for said purposes and for pain associated with dysmennorrhea (menstrual pain)defendants trained their sales force to distribute "pain packs" consisting of fourteen sample pills of Celebrex® and Bextra® to physicians who did not treat arthritis patients, such as surgeons, oncologists, emergency room

doctors, podiatrists and even psychiatrists. The sales force was trained to suggest that these physicians give the pain packs to their patients for the treatment of all types of pain.

21. As part of the illegal off-label promotion of Celebrex® and Bextra®, defendants provided members of its sales force with data sheets showing how many Celebrex® and Bextra® prescriptions were being written by each physician in that sales person's territory, and how many prescriptions were being paid for by Medicare and Medicaid as opposed to private health insurance companies. The sales force initially targeted physicians who wrote prescriptions mainly for Medicare and Medicaid patients because these programs generally did not require prior authorizations like some of the private insurers.

22. As part of the illegal off-label promotion of Celebrex®, defendants provided members of its sales force with "home made sales kits" containing "merged" medical studies that could be used to market Celebrex® to physicians for off-label uses. In such studies, data from multiple studies was "merged" by sales representatives having little or no knowledge of the significance of the scientific, pharmacological or epidemiological information contained therein. The only concern in preparing these merged studies was to insure that the data favored Celebrex® over the comparison drug. Once such study compared Celebrex® to Vicodin®, which is not eve an anti-inflammatory in the same class of drug as Celebrex®.

23. Federal laws and regulations governing Medicare and Medicaid programs prohibit the payment of kickbacks to medical care providers. *See* 42 U.S.C. §1320a-7b(b)(2). Unlawful kickbacks include payments, gratuities and other benefits paid to prescribers in order to induce such person to purchase a prescription drug for which payment is to be made under the Medicare or Medicaid programs.

24. As part of the illegal off-label promotion of Celebrex® and Bextra®, defendants caused their sales force to pay kickbacks to physicians who prescribed Celebrex® and Bextra® for off-label purposes. Such kickbacks took the form of cash payments, travel, meals, happy hours, and entertainment for such physicians.

25. The amount reimbursed for prescription drugs under the Medicaid program is subject to price controls based on the price of other drugs that are determined by the FDA to be therapeutically equivalent. *See* 42 U.S.C. § 1396r-8(e). Defendants' illegal program of off-label promotion and avoidance of proper FDA procedures for approval of a new drug uses has resulted in the lack of any classification of Celebrex® and Bextra® for therapeutic equivalency as to its off-label uses, such as general pain relief. As a result, Celebrex® and Bextra® have not been subject to federal Medicaid price limits based on therapeutic equivalency.

26. The United States Government has been harmed by the absence of therapeutic equivalents for Celebrex® and Bextra® in connection with their off-label uses since the Medicaid program is paying for these drugs instead of for less-expensive alternatives (such as over-the-counter NSAIDS) that confer the same or greater benefit for off-label uses.

27. Defendants' illegal promotional activities were undertaken the intent of, and had the effect of, inducing physicians to increase their off-label prescription of Celebrex® and Bextra®. Defendants knew that some portion of the prescriptions for off-label purposes would be given to patients whose prescription drug costs would be reimbursed under the Medicaid program.

28. On information and belief, Defendants' off-label promotion of Celebrex® and Bextra® caused false claims for payment to be submitted to the Medicaid program. Such claims were false in two respects. First, some of the claims sought payment under the Medicaid

programs in States that did not cover prescription drugs for off-label uses. Such claims were false to the extent that they represented that the cost of Celebrex® and/or Bextra® was properly reimbursable under the Medicaid program in such States. Second, each claim submitted as a result of a prescription written by a physician who had received illegal kickbacks from the defendants contained a false implied representation that the claim complied in all material respects with the law governing the Medicaid program.

29. Defendants knew that its unlawful promotional efforts would result in the submission of false claims to the United States Government, or acted with reckless disregard for whether such claims would contain false information.

30. Defendants' conduct constitutes a violation of 31 U.S.C. § 3729(a)(1).

Count II
False Statements Inducing Direct Sales to the United States

31. The allegations set forth in paragraphs 1-30 above are hereby incorporated by reference as though fully set forth herein.

32. As part of the illegal off-label promotion of Celebrex® and Bextra®, defendants caused their sales force to market Celebrex® and Bextra® directly to the United States Armed Services and Veterans Administration for off-label uses. Such marketing efforts included misrepresentations made to physicians employed by the United States Government as to the safety and efficacy of these drugs relative to their proposed off-label uses.

33. By this conduct, defendants knowingly caused to be made and used false statements in order to get a false or fraudulent claim approved and paid by the United States Government, in violation of 31 U.S.C. § 2729(a)(2).

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray for judgment on behalf of the United States, together with all costs, attorneys' fees, awards and interest allowed by 31 U.S.C. § 3730.

PLAINTIFF DEMANDS A JURY TRIAL

Respectfully submitted,

UNITED STATES OF AMERICA, BY AND THROUGH THE RELATORS, ROBERT WILLSON, RICHARD EHLERS, and CRAIG WATKINS

By their attorneys,

Denis M. King (BBO No. 555838)
GOULSTON & STORRS, P.C.
400 Atlantic Avenue
Boston, MA 02110-3333
(617) 482-1776

Thomas P. Cartmell
Brian J. Madden
Thomas J. Preuss
WAGSTAFF & CARTMELL LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
(816) 701-1100